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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,402	10/11/2005	David Paul Humphreys	CELL-0294	8981

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EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
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1636

MAIL DATE	DELIVERY MODE
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10/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,402

Applicant(s)

HUMPHREYS ET AL.

Examiner

Nancy T. Vogel

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/8/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-12 are pending in the case.

Receipt of the Information Disclosure Statement on 12/8/05 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and by dependence claims 2-12, are vague and indefinite in the recitation of "an E. coli host cell comprising at least one genetic alteration that results in...that when unmodified, co-purifies with a recombinant antibody expressed by said host cell", since it is unclear from the claim whether it is intended to claim a host cell that expresses a recombinant antibody. From the language used, it could be interpreted that the phrase "co-purifies with a recombinant antibody expressed by the host cell" is intended to refer to a property of the endogenous protein only, and not to the actual host cell claimed. For the purposes of examination only, the latter interpretation has been used.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Shuman et al. (J. Biol. Chem., 257, 10:5455-5461, 1982).

Shuman discloses an E. coli strain comprising a deletion of the gene encoding maltose binding protein, which would affect the isoelectric point (see Table I, strain HS2019, see). It is noted that the claims do not require that a recombinant antibody is expressed in the host cell; rather, the claim recites that the alteration present in the cell results in modification of a physical property of an endogenous protein that, when unmodified, co-purifies with a recombinant antibody expressed by the cell. The phrase “when unmodified, co-purifies with a recombinant antibody expressed by the cell” describes the identity of the protein that is modified.

Claims 1-5, 11, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Joly et al. (WO 98 18946) (cited by applicants).

Joly et al. disclose E. coli strains comprising at least one genetic alteration that results in modification of at least one physical property of at least one endogenous protein that co-purifies with a recombinant antibody expressed by the cell, which is PtsS (see page 3; see page 5, line 25- page 6, line 10). The reference discloses a method of producing a heterologous protein, which may be an antibody, comprising fermenting said strain.

Claims 1-5, 11, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bass et al. (US Patent 5,304,472)(cited by applicants).

Bass et al. disclose E. coli strains comprising at least one genetic alteration that results in modification of at least one physical property of at least one endogenous protein that co-purifies with a recombinant antibody expressed by the cell which is PtsS (see col. 3 line 45 – col. 4 line 18; see col. 7-8). The reference discloses a method of producing a heterologous protein, which may be an antibody, comprising fermenting said strain.

Claims 1-5, 11, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Oppen et al. (EP 737747) (cited by applicant).

Oppen et al. disclose E. coli strains comprising at least one genetic alteration that results in modification of at least one physical property of at least one endogenous protein that co-purifies with a recombinant antibody expressed by the cell which is thioredoxin 1 (see abstract). The reference discloses a method of producing a heterologous protein, which may be an antibody, comprising fermenting said strain (see abstract).

Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NV
10/5/07


NANCY VOGEL
PRIMARY EXAMINER